K082705

KLS martin L.P.

JUN 12 2009

# 510(K) SUMMARY

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| **Submitter:** | KLS-Martin, L.P.<br>11239-1 St. Johns Industrial Parkway South<br>Jacksonville, FL 32246<br>Phone: 904-641-7746<br>Fax: 904-641-7378 |
| **Contact Person:** | Tom Faucett<br>Product Marketing Liaison |
| **Date of Summary:** | 18 May 2009 |
| **Device Name:** | Electrosurgical Instruments |
| **Trade Name:** | KLS Martin Electrosurgical Instruments |
| **Common Name:** | Electrosurgical, Cutting & Coagulation & Accessories |
| **Classification Name and Number:** | Electrosurgical, Cutting & Coagulation & Accessories (CFR 878.4400) |
| **Regulatory Class:** | II |
| **Predicate Devices:** | Claris Non-Stick Bipolar Forceps (K051429)<br><br>BiTech Bipolar Scissors (K042077)<br><br>POWERGRIP Bipolar Coagulation Forceps (K033177)<br><br>Bissinger Cables (K981919)<br><br>Bissinger Detachable Bipolar Coagulation Forceps (K970968) |
| **Intended Use:** | KLS Martin Bipolar Scissors are intended for dissecting, cutting and bipolar coagulation of tissue during general surgical procedures.<br><br>KLS Martin Bipolar Instruments with Handles and Exchangeable Electrodes are intended for grasping, dissecting, cutting and bipolar |

coagulation of tissue during general, gynecology and laparoscopic surgical procedures.

KLS Martin marLap Bipolar Coagulation instruments are intended for grasping, dissecting, cutting and bipolar coagulation of tissue during general, gynecology and laparoscopic surgical procedures.

KLS Martin Bipolar Forceps/Non-Stick are design to grasp, manipulate and coagulate selected tissue.

KLS Martin Electrosurgical Instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures

KLS Martin Electrosurgical cables are intended for use in electrosurgical procedures to provide transmission of electrical power from the bipolar electrosurgical generator to a bipolar instrument.

**Device Description:**

The KLS Martin Electrosurgical Instruments are surgical instruments that allow the surgeon to cauterize and coagulate tissue by passing a electrical current that is provided by a electrosurgical generator. The instruments are insulated to isolate the user from the current. The KLS Martin Electrosurgical Instruments are manufactured in a variety of shapes and sizes to allow the operating surgeon choices for optimum efficiency.

**Technological Characteristics:**

**Similarities to Predicate:**

The KLS Martin Electrosurgical Instruments are identical in design, manufacturing, material and operation to the Claris Non-Stick Bipolar Forceps (K051429), BiTech Bipolar Scissors (K042077), POWERGRIP Bipolar Coagulation Forceps (K033177), Bissinger Cables

(K981919) and Bissinger Detachable Bipolar Coagulation Forceps (K970968).

**Substantial Equivalence:**

Due to identical operating aspects, the design, the ability to be utilized with multiple generators and the same manufacturing facility as the Claris Non-Stick Bipolar Forceps (K051429), BiTech Bipolar Scissors (K042077), POWERGRIP Bipolar Coagulation Forceps (K033177), Bissinger Cables (K981919) and Bissinger Detachable Bipolar Coagulation Forceps (K970968) and have the same indications for use leads to the decision that the KLS Martin Electrosurgical Instruments are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2009

KLS Martin L.P.
% Mr. Tom Faucett
Product Marketing Liaison
11239-1 St. Johns Industrial Parkway South
Jacksonville, Florida 32246

Re: K082505
Trade/Device Name: KLS Martin Electrosurgical Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Code: GEI
Dated: April 28, 2009
Received: May 21, 2009

Dear Mr. Faucett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

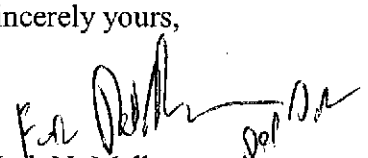
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing

practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082505

# Indications for Use

510(k) Number (if known): K082505

Device Name: KLS Martin Electrosurgical Instruments

Indications For Use: KLS Martin Bipolar Scissors are intended for dissecting, cutting and bipolar coagulation of tissue during general surgical procedures.

KLS Martin Bipolar Instruments with Handles and Exchangeable Electrodes are intended for grasping, dissecting, cutting and bipolar coagulation of tissue during general, gynecology and laparoscopic surgical procedures.

KLS Martin marLap Bipolar Coagulation instruments are intended for grasping, dissecting, cutting and bipolar coagulation of tissue during general, gynecology and laparoscopic surgical procedures.

KLS Martin Bipolar Forceps/Non-Stick are design to grasp, manipulate and coagulate selected tissue.

KLS Martin Electrosurgical Instruments have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures

KLS Martin Electrosurgical cables are intended for use in electrosurgical procedures to provide transmission of electrical power from the bipolar electrosurgical generator to a bipolar instrument.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082505